

K000587

MAY - 4 2000

**510(k) Summary
for
SHUTTLE STOP**

1. SPONSOR

IsoTis BV
Prof. Bronkhorstlaan 10
3723 MB Bilthoven
The Netherlands

Contact Person: E. Schutte, MSC.
Telephone: +31-(0) 30-2295253

Date Prepared: February 18, 2000

2. DEVICE NAME

Proprietary Name: Shuttle Stop
Common/Usual Name: Cement restrictor
Classification Name: Cement obturator

3. PREDICATE DEVICES

- Tornier Cement Restrictor (K973453)
- BIOSTOP® G Bone Cement Restrictor (K943727)

4. DEVICE DESCRIPTION

The IsoTis Shuttle Stop is a polymeric intramedullary cement plug that is inserted into the intramedullary canal during implantation of a joint prosthesis to prevent the migration of bone cement. The device has a conical shape and is available in four sizes to cover the plugging of most intramedullary canals.

5. INTENDED USE

The Shuttle Stop is a conical-shaped plug intended for intramedullary occlusion during cemented hip and shoulder arthroplasty.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed and previously cleared devices are plugs that are inserted into the intramedullary canal during implantation of a prosthetic joint to prevent migration of bone cement.

The BIOSTOP® G has a cylindrical shape with deeply grooved sidewalls and a rounded tip. The proposed Shuttle Stop has a conical shape with smooth sidewalls. The Shuttle Stop and BIOSTOP® G are available in a variety of sizes to fit most medullary canals (8 to 20 mm). The Tornier device is fan-shaped and assumes a cylindrical shape once implanted.

The proposed device and the Tornier predicate are constructed of different forms of plastic. The BIOSTOP® G device is composed of a glycerol/gelatin/water compound and is bioresorbable. The Shuttle Stop is manufactured of a bioresorbable copolymer.

Based on the similarities in intended use and technological characteristics, IsoTis believes that the Shuttle Stop is substantially equivalent to the Tornier Cement Restrictor, and BIOSTOP® G Bone Cement Restrictor.

7. TESTING

Biocompatibility testing performed on finished devices demonstrated that the Shuttle Stop meets the requirements of ISO 10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" for an implant device with permanent tissue/bone contact. In addition to the testing required to satisfy the requirements of ISO 10993, the device also passed the USP Rabbit Pyrogen Test and LAL test for pyrogenicity.

The safety and effectiveness of the Shuttle Stop has been compared with a polyethylene cement restrictor in a randomized prospective clinical trial conducted in 1995. Ninety-seven patients were enrolled in the study with a follow-up time frame

of 24 months. The results show no evidence of adverse effects associated with use of the Shuttle Stop. Harris Hip scores and plug migration was similar to those of the polyethylene plug. However, the incidence and extent of leakage observed was significantly less for the Shuttle Stop than the polyethylene device. The report concludes that the Shuttle Stop is safe and effective for its intended use and performs significantly better than the polyethylene standard of care in the prevention of leakage.

Testing was also performed to support a two-year shelf life.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cynthia J.M. Nolte, Ph.D.
Representing
IsoTis BV
Prof. Bronkhorstlaan 10
3723 MB Bilthoven
P.O. Box 98, 3720 AB Bithoven
The Netherlands

Re: K000587
Trade Name: Shuttle Stop
Regulatory Class: II
Product Code: LZN
Dated: February 18, 2000
Received: February 22, 2000

Dear Dr. Nolte:

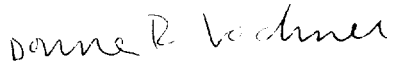
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000587

Device Name: Shuttle Stop

Indications for Use:

The Shuttle Stop is a conical-shaped plug intended for intramedullary occlusion during cemented hip and shoulder arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER
PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000587

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)